UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,795	04/21/2004	Eckard Weber	OREX.001A	5046

20995 7590 04/05/2007

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
KWON, BRIAN YONG S	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	04/05/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 04/05/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,795	WEBER ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11,24-26,29-31 and 34-49* is/are pending in the application.

4a) Of the above claim(s) *10,11,24-26,29-31,34,35,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-9, 36-43 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/06/06, 1/23/07, 1/25/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner for the instant application has changed. The current examiner assigned to this application is Brian-Yong S. Kwon.

2. Claims 8-11, 24-26, 29-31 and 34-49 are pending in the application.

3. Looking at the prosecution history, the Election/Restriction requirement was issued on 07/27/2006. In response to the requirement, the applicant elected Group I invention along with naltrexone and bupropion as the elected species on 08/08/2006. Accordingly, claims 10-11, 24-26, 29-31 and 34-35 were withdrawn from further consideration by the examiner as being drawn to a non-elected invention.

4. Acknowledgment is made of the applicant's filing of amendment and remarks on 01/23/07. By the amendment, claims 8, 9, 10, 25, 26, 30, 31, 35, 36 and 37 were amended; claims 19, 22-23, 27-28 and 32-33 were cancelled; and claims 38-49 were newly added.

With respect to the newly added claims 44-45, the composition of the claims 44-45 which requires of zonisamide as third compound in said composition are directed to an invention that is independent or distinct from the invention originally elected invention which are drawn to a composition comprising naltrexone as 1st compound and bupropion as 2nd compound.

It is noted that applicant has received an action on the merits for the originally elected invention which is directed to a composition comprising naltrexone in combination with bupropion. Accordingly, claims 44 and 45 will be withdrawn from further consideration by the examiner as being drawn to a non-elected invention.

Claims 38-43 and 46-49 will be grouped together with the previously examined claims 8-9 and 36-37. Claims 8-9, 36-43 and 46-49 are currently pending for prosecution on the merits of the case.

5. Applicant's arguments, filed 01/23/2007, with respect to the rejection(s) of claim(s) 8-9 and 36-37 under 35 USC 102(b) as being anticipated by Dante (USP'665) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

6. Applicant's amendment requiring "a sustained release formulation of a weight loss affecting amount" in claim 8 necessitates a new ground of rejection(s) in this Office Action.

Information Disclosure Statement

7. Acknowledgement is made of applicant's submitting of the information disclosure statements (IDS) on 10/06/2006, 01/23/2007 and 01/25/2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement (IDS) has been considered by the examiner.

With respect to Cite No. 23-28 (the International Search Reports) in the submitted PTO-1449, the information disclosure statement filed 01/23/2007 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for

consideration by the Office. Accordingly, it has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 8-9, 36-43 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Malley et al. (US 6004970).

O'Malley discloses a composition comprising an opioid antagonist (i.e., naltrexone) in combination with nicotine and antidepressant (i.e., bupropion hydrochloride or Wellbutrin) that is useful for the treatment of smoking cessation, wherein said composition is prepared and administered in various dosage forms including oral, intravenous, intramuscular or intradermal, e.g., by sterile injections, including depot versions, implants, parenteral administration; wherein naltrexone is administered in 2 to 10mg (bolus), 0.2 to 1.0 mg/hr (a continuous drip) or 25 to 100mg (oral); and wherein said composition is delivered in a sustained release preparation (column 2, line 66 through column 3, line 17; column 3, lines 58-67; column 4, lines 18-26; column 5, lines 27-33; column 6, lines 1-14; and claims 11-13 and 16-17).

With respect to the specific amounts of bupropion, "about 30mg to about 300mg", in claims 39-43, the examiner determines that such amounts deems to be inherent to the known antidepressant amount or antismoking cessation amount of bupropion (see column 4, lines 32-38 of USP 6197827 for your reference: USP'827 discloses a range of about 50 mg to about 300 mg

per day of bupropion as antidepressant amount or antismoking amount). Therefore, O'Malley anticipates the claimed invention.

With respect to the instantly claimed "a weight loss affecting amount", since the referenced amounts of naltrexone and antidepressant amount of bupropion overlap with the instant "weight loss affecting amount" of naltrexone and bupropion (which about 5mg to about 50mg of naltrexone and about 30mg to 300mg of bupropion), O'Malley anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 8-9, 36-43 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dante (USP 5817665) in view of applicant's admission of the prior art of record (para. [0100]), and further in view of Chen et al. (US 6210716 B1) and Cook (US 6071918).

Dante discloses a composition comprising a pharmacologically effective dose of a compound of opioid antagonists (i.e., naltrexone) and a pharmacologically effective dose of a compound of nontricyclic antidepressants (i.e., bupropion) that is useful for the treatment of depression (claims 9 and 12).

Applicant admits that various sustained-release materials have been established and are well known by those skilled in the art.

Chen and Cook are being supplied as references to demonstrate the routine knowledge in preparing naltrexone and bupropion in controlled or sustained release formulation.

The teaching of Dante differs from the claimed invention in preparing said composition in sustained release formulation. To incorporate such teaching into the teaching of Dante, would have been obvious in view of Applicant's admission and/or USP'716 and USP'918 that the preparing naltrexone and bupropion in controlled or sustained release formulation is well known in the art.

One having ordinary skill in the art would have been motivated to make such modification, with the reasonable expectation of success, to extend the usage of the claimed composition by preparing said composition in sustained release formulation to accommodate patients' preference

and needs where the compliance could be improved with effective and well tolerated dosage regimen.

As discussed above, the applicant's statement of "the affecting weight loss" is not limited to the interpretation of the composition claims since such property or characteristic deems to be expected feature (inherent) of the referenced composition (due to overlapping dosage amounts). Thus, the cited references in combination make obvious the instant invention.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614